

## **REMARKS**

### **A. Priority**

The Office Action states that applicant's specific references to the 09/280,181 application should be updated to reflect the fact that the '181 application has issued as U.S. Patent No. 6,280,941. Applicant has amended the specification to reflect this.

### **B. Information Disclosure Statement**

The Office Action states that the IDS filed February 1, 2002 fails to comply with 37 C.F.R. 1.98(a)(2) because copies of reference number 58 (Drake) and foreign patent document FR 2707 011 A were not provided. Applicant has submitted concurrently with the present response a new IDS accompanied by copies of each of these references.

### **C. Claim rejections – 35 U.S.C. §112, second paragraph**

Claims 1-19 are rejected under 35 U.S.C. §112, second paragraph, as indefinite and failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

The Office Action states that claims 1-9 are indefinite over the recitation of the phrase "wherein said CA dinucleotide repeat sequence is located in the genomic sequence upstream from a PARP transcription start site, corresponding to nucleotide positions 846 through 869 of (SEQ. ID. NO.:5)" in claim 1. Applicant has amended claim 1 to remove this phrase.

The Office Action states that claim 2 is further indefinite over the recitation of the phrase "wherein said eighteen-fold CA dinucleotide repeat sequence is located in the genomic sequence upstream from a PARP transcription start site, between nucleotides

845 and 869 of (SEQ. ID. NO.:5)." Applicant has amended claim 2 to remove this phrase.

The Office Action states that claims 9 and 19 are indefinite due to the recitation of the trademarked terms SYBR and YO-PRO. According to the Office Action, the use of these terms renders the claims vague and indefinite. Applicant respectfully asserts that the names in question (SYBR Green I and YO-PRO-1) constitute the only convenient means for identifying these dyes. Further, Applicant asserts that the dyes in question are well known and widely used in the art, making it unlikely that the product associated with these names will change. This is illustrated in part by the fact that both of these names regularly appear in patent claim language. For example, the term SYBR Green I is found in the claim language of U.S. Patent No's. 6,297,014 (Taylor), 6,346,386 (Elenitoba-Johnson), 6,365,341 (Wu), 6,558,929 (Thum), and 6,656,692 (Erikson), while the term YO-PRO-1 is found in the claim language of U.S. Patent No's. 6,297,014 (Taylor), 6,312,930 (Tice), 6,346,386 (Elenitoba-Johnson), 6,472,168 (Matsumoto), and 6,656,692 (Erikson). Based on this, Applicant respectfully asserts that the terms "SYBR Green I" and "YO-PRO-1" constitute the best means for identifying the dyes in question.

The Office Action states that claims 10-11 are indefinite. Applicant has canceled these claims, rendering this rejection moot.

The Office Action states that claims 12-19 are indefinite over the recitation of the phrase "wherein said eighteen-fold CA dinucleotide repeat sequence is located in the genomic sequence upstream from a PARP transcription start site, between nucleotide

positions 845 and 869 of (SEQ. ID. NO.:5)" in claim 12. Applicant has amended claim 12 to remove this phrase.

#### **D. Claim rejections – 35 U.S.C. §103**

Claim 10-11 are rejected under 35 U.S.C. §103 as obvious over Fougrousse in view of Ahern. Applicant has canceled claims 10 and 11, rendering this rejection moot.

#### **E. Claim rejections – double patenting**

Claims 1-9 and 12-19 are rejected under the judicially created doctrine of obviousness-type double patenting in light of claim 1-4 of U.S. Patent No. 6,280,941 B1 ("the '941 patent"). According to the Office Action, claims 1-9 and 12-19 are not patentably distinct from claims 1-4 of the '941 patent, because they are either anticipated by or obvious over those claims. The Office Action goes on to state that claims 1-9 and 12-19 are generic to all that is recited in claims 1-4, i.e., they are anticipated by claims 1-4. According to the Office Action, both claim sets recite the steps of collecting tissue, amplifying nucleic acids, and detecting amplification products to identify SLE predisposition, and the primers of claims 1-4 from the '941 patent are the same as those of instant dependent claims 5-7 and 15-17.

Applicant respectfully asserts that the present claims are not anticipated by the claims of the '941 patent. The Office Action is correct in stating that both claim sets recite the steps of collecting tissue, amplifying nucleic acids, and detecting amplification products to identify SLE predisposition. However, the claim sets differ in how they identify SLE predisposition. Claims 1-4 of the '941 patent utilize two specific primers (SEQ. ID. NO.:1 and SEQ. ID. NO.:2) for amplification. Following amplification, SLE predisposition is determined based only on the size of the amplification products, with

no consideration given to the sequence of those amplification products. The claims of the present invention, on the other hand, identify SLE predisposition based on the nucleotide sequence of the amplification products. Rather than being limited to the use of two specific primers, this method allows the use of any primer set that amplifies the region between D1S2860 and D1S213. Following amplification, amplification products are analyzed for the presence of either a twelve-fold or an eighteen-fold CA dinucleotide repeat. This method allows for a more precise determination of SLE susceptibility using a wider range of amplification primers. As such, the claims of the present invention are not anticipated by claims 1-4 of the '941 patent.

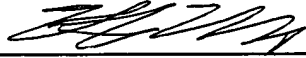
Claims 10-11 are rejected under the judicially created doctrine of obviousness-type double patenting. Applicant has canceled claims 10-11, rendering this rejection moot.

### **CONCLUSION**

In view of the foregoing, it is submitted that the present claims are in condition for allowance. Accordingly, Applicant respectfully requests that a Notice of Allowance be issued.

Respectfully submitted,  
Perkins Coie LLP

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